

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION This document relates to: Emma Willie, 18-3857)))))))	MDL No. 16-2740 SECTION: “H” (5)
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ORDER AND REASONS

Before the Court is a Motion for Summary Judgment on Warnings Causation (Doc. 12202). The Court held oral argument on the Motion on April 14, 2021. For the following reasons, the Motion is **GRANTED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, “Sanofi” or “Defendants”). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second is set for 2021.²

¹ Docetaxel is the generic version of Taxotere.

² The second trial was continued due to the COVID-19 pandemic.

In December 2020, the Court selected Plaintiff Emma Willie to proceed with discovery in preparation for the fourth bellwether trial.³ Plaintiff Willie was diagnosed with an early stage breast cancer in October 2014 at the age of 54.⁴ At the recommendation of her oncologist, Dr. Sadanand Patil, Willie underwent a lumpectomy.⁵ During the procedure, doctors realized that the cancer had spread to one of Willie's lymph nodes.⁶ After this, Dr. Patil recommended chemotherapy, and Willie began receiving Taxotere and Cyclophosphamide.⁷ She is now cancer-free, and she has joined this MDL alleging that she suffers permanent hair loss from Taxotere.

The parties agree that Mississippi law governs this suit. In the instant Motion, Sanofi seeks summary judgment, arguing that under Mississippi's learned intermediary doctrine, Plaintiff Willie cannot establish the essential element of causation in her case. Plaintiff opposes the Motion.

LEGAL STANDARD

Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.”⁸ A genuine issue of fact exists only “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.”⁹ “In reviewing a summary judgment motion, the court must ‘refrain from making credibility determinations or weighing the

³ The Court selected two other Plaintiffs as well—Cindy Smith and Melissa Roach. *See* Doc. 11722.

⁴ *See* Doc. 12202-2 at 2; Doc. 12280-1 at 1–2.

⁵ Doc. 12202-2 at 2.

⁶ *Id.*; Doc. 12280-1 at 2.

⁷ Doc. 12202-2 at 3; Doc. 12280-1 at 2, 3.

⁸ *Sherman v. Hallbauer*, 455 F.2d 1236, 1241 (5th Cir. 1972).

⁹ *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

evidence’ and must view the facts in the light most favorable to the non-moving party and draw all reasonable inferences in its favor.”¹⁰

LAW AND ANALYSIS

Sanofi argues that Plaintiff has failed to carry her burden of showing that a different warning in the Taxotere label would have changed her doctor’s prescribing decision. Sanofi emphasizes that Plaintiff’s oncologist, Dr. Patil, testified that despite becoming aware of Taxotere’s risk of permanent alopecia, if Willie came to see him today with the same diagnosis, he would recommend the same regimen. Citing this Court’s prior opinions, Sanofi acknowledges that patient choice factors into the prescribing decision, but Sanofi avers that Plaintiff Willie trusted Dr. Patil and would have followed his recommendation even if she had been warned of a risk of permanent hair loss.

In response, Plaintiff argues that this case presents a genuine issue of fact for the jury to resolve. Plaintiff avers that if Dr. Patil had known of a risk of permanent alopecia associated with Taxotere, he would have advised Willie about the risk. According to Plaintiff, she then would have elected not to take Taxotere, and Dr. Patil would have offered her other options. In support of this, Plaintiff emphasizes testimony from Dr. Patil saying that patients “make all the choices” as far as treatment.¹¹

As the parties acknowledge, Mississippi follows the learned intermediary doctrine in cases involving prescription drugs.¹² “Under this doctrine, the manufacturer’s failure to warn the patient of the product’s risks

¹⁰ *Devon Enterprises, LLC v. Arlington Independent School Dist.*, 541 Fed. App’x 439, 441 (5th Cir. 2013).

¹¹ Doc. 12280 at 4.

¹² *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th. Cir. 1992).

does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary.”¹³ Consistent with this, a plaintiff bringing a failure to warn claim must establish (1) that an adequate warning would have prevented the treating physician—the learned intermediary—from administering the drug; and (2) that the injury would not have occurred had the drug not been administered.¹⁴

Defendants have pointed to sufficient evidence showing that Plaintiff cannot establish causation. As an initial matter, the Court assumes, viewing the facts in the light most favorable to Plaintiff, that Dr. Patil would have warned Plaintiff Willie of a risk of permanent hair loss, had he known of it. He testified that now, after reading the revised Taxotere label, he “would probably tell [patients] that there is a chance that their hair might not come back.”¹⁵ However, he also testified that if Willie came to him today with the same diagnosis, he would still recommend the same Taxotere-containing regimen that he recommended to her years ago.¹⁶ He explained as follows:

A: There are certain -- there are basically two major options for treating early stage breast cancer. One is a combination of -- called AC times four followed by taxol times four, and the other one is TC. The other option is much more toxic and has the potential for cardiac toxicity, and we only -- we generally reserve it for patients who have a certain kind of breast cancer called HER2-positive breast cancers where that is more effective. Otherwise, [for] everybody else I use the TC combination.

¹³ *Id.*

¹⁴ *See id.* at 814.

¹⁵ Doc. 12280-2 at 8.

¹⁶ Doc. 12202-5 at 6.

Q: Thank you. So with respect to her specific category of early stage breast cancer, your clinical experience has been to use TC?

A: That's correct.¹⁷

Summing up this testimony, he stated that “[u]nless the patients have the HER2-positive kind of breast cancer, the default is TC.”¹⁸

Significantly, and consistent with the above, Dr. Patil offered Plaintiff Willie *only* the TC option; his testimony makes clear that he would have offered her another option—the AC—*only* if she had refused the TC:

Q: Would you have explained to Ms. Willie other treatment options that would have been available to her if she did not elect to take TC?

A: If she had refused to take TC, yes, but this would be my first recommendation. She was not HER2-positive, so this would be my recommendation, so we did not offer her other options.¹⁹

Before prescribing the AC, however, Dr. Patil would have ordered an echocardiogram of Plaintiff's heart:

Q: [. . .] [S]peaking in this hypothetical situation where Ms. Willie says to you, I don't want Taxotere and she informs you she wants the A and C option, you would have been obligated under your standard of care to actually have her evaluated by a cardiologist to see if she would be an appropriate candidate; true?

A: True.

Q: Okay. And just for the jury's benefit, why do you do that? Why do you send your patients to a cardiologist before you even consider giving them the A and the C?

¹⁷ *Id.* at 4–5.

¹⁸ *Id.*

¹⁹ *Id.* at 5.

A: We don't actually send them to a cardiologist. The cardiologist does the echocardiogram, and we look at the report of the echocardiogram.

Q: Okay. Very good. And so had Ms. Willie said, I don't want T, I want the A and C, you would not have necessarily given her the A and C until she had additional evaluation done; true?

A: Yes, I would not have given it to her.²⁰

Plaintiff emphasizes testimony from Dr. Patil saying that when there are choices, he encourages a patient to be an active participant in deciding which chemotherapy regimen to use.²¹ Indeed, he testified that “[t]hey have all the choice. They make the choice of getting treatment, the options of treatment. They make all the choices.”²² To an extent, then, Dr. Patil allows his patients to guide his prescribing decisions.

With this in mind, the Court considers Willie's testimony:

Q: And you were relying on Dr. Patil at that time to recommend the most effective treatment for you?

[. . .]

A: Yes. I mean, he was the doctor. He was oncologist, so he knew more about it than I did. So, yeah, I was relying on him to -- yeah.²³

She further testified that she “really didn't have any” questions for Dr. Patil and that she was focused on survival.²⁴ In response to his recommendation of a lumpectomy, she asked whether the more invasive mastectomy would be more effective; she was concerned that the cancer could come back.²⁵ This

²⁰ *Id.* at 13.

²¹ Doc. 12280-2 at 10.

²² *Id.*

²³ Doc. 12202-10 at 5.

²⁴ *Id.*

²⁵ *See id.*

evinces that Plaintiff was indeed sharply focused on survival. Ultimately, she followed the recommendation of Dr. Patil and underwent a lumpectomy.²⁶

Her other testimony similarly shows that she trusted Dr. Patil:

Q: So it was Dr. Patil's opinion at that appointment that you did need chemotherapy; is that correct.

A: Correct.

Q: And did you agree with him on that?

[. . .]

A: Well, I mean, he recommended it, so, you know.

Q: You trusted him to make the right recommendation for your cancer?

A: Right.

Q: Did you do any additional research before you made that decision aside from talking to Dr. Patil?

A: No.²⁷

When asked if she would have followed his recommendation regardless of what it was, she testified that "if [Dr. Patil] recommended it, then I was going to follow it because that's what he recommended."²⁸ Her testimony was unequivocal. She stated, too, that "him being the doctor, I wanted to follow what he said because I wanted to be cancer-free."²⁹

In her opposition, Plaintiff seizes upon this quote from her deposition: "If it had of been some other type of treatment that wouldn't have taken my hair or whatever, you know, I probably would have gone with that or whatever."³⁰ This testimony alone, however, is not enough to create an issue of fact. As

²⁶ See *id.* at 5, 7.

²⁷ *Id.* at 9.

²⁸ *Id.* at 12.

²⁹ *Id.*

³⁰ Doc. 12280 at 8–9.

explained, the record shows that Plaintiff was focused on survival and that she trusted Dr. Patil. The record does not support the idea that Willie would have asked for other options, refused the TC regimen, or chosen the “more toxic” AC regimen known for cardiac toxicity.³¹ Instead, a reasonable jury could only find that Willie would not have gone against Dr. Patil’s recommendation to take a Taxotere-containing regimen, even if it meant risking permanent hair loss. She stated, “hair loss or live? I mean, who wouldn’t take the living over hair loss, I mean?”³² Based on the record, then, the Court must grant Sanofi’s Motion.

CONCLUSION

Accordingly, for the foregoing reasons, Sanofi’s Motion for Summary Judgment on Warnings Causation (Doc. 12202) is **GRANTED**. Plaintiff Emma Willie’s case is **DISMISSED WITH PREJUDICE**;

IT IS FURTHER ORDERED that Sanofi’s Motion for Summary Judgment Under the Doctrine of Judicial Estoppel as to the Claims of Plaintiff Emma Willie (Doc. 12201) is **DISMISSED AS MOOT**.

³¹ She testified as follows:

Q. If there was another option for chemotherapy and it didn’t have the risk of permanent hair loss but it had the risk of permanent heart failure, would you take the regimen that had the risk of permanent heart failure? A. Over the hair loss regimen?

[. . .]

A. No. I mean, like I said, no. You know, hair loss or live. You know, no, I would take the one that -- that -- you know, at least if I have a loss of hair I’m still living. So, no, I would take the one with the hair loss.

Doc. 12202-10 at 14. Again, the Court emphasizes that Dr. Patil did not offer Plaintiff any other options; Plaintiff would have had to refuse the TC before another option even entered the conversation.

³² *Id.*

New Orleans, Louisiana, this 16th day of April, 2021.

A handwritten signature in black ink, appearing to read "Jane Triche Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE